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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/648,864	08/25/2000	Howard M Johnson	UF-243X	6790

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EXAMINER	
ANDRES, JANET L	
ART UNIT	**PAPER NUMBER**
1646	

DATE MAILED: 08/13/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action	Application No.	Applicant(s)	
	09/648,864	JOHNSON ET AL.	
	Examiner	Art Unit	
	Janet L. Andres	1646	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 06 July 2004 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

a) ☒ The period for reply expires *6* months from the mailing date of the final rejection.

b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1.☒ A Notice of Appeal was filed on *26 July 2004*. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.

2.☐ The proposed amendment(s) will not be entered because:

(a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);

(b) ☐ they raise the issue of new matter (see Note below);

(c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or

(d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____.

3.☐ Applicant's reply has overcome the following rejection(s): _____.

4.☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

5.☒ The a)☐ affidavit, b)☐ exhibit, or c)☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: *See Continuation Sheet*.

6.☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

7.☒ For purposes of Appeal, the proposed amendment(s) a)☐ will not be entered or b)☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: _____.

Claim(s) objected to: _____.

Claim(s) rejected: *25,30-32,34-45 and 47-55*.

Claim(s) withdrawn from consideration: _____.

8.☐ The drawing correction filed on _____ is a)☐ approved or b)☐ disapproved by the Examiner.

9.☐ Note the attached Information Disclosure Statement(s)(PTO-1449) Paper No(s). _____.

10.☐ Other: _____

JANET ANDRES
PRIMARY EXAMINER

Continuation of 5. does NOT place the application in condition for allowance because: Applicant argues that inherency must be recognized by the skilled artisan, citing in re Crown Operations. Applicant argues that the methods are different from the prior art because they are methods for suppressing or inhibiting IgE-mediated allergy and because they now recite treatment of a patient in need of such treatment. Applicant argues that the cited refeernces do not teach each and every aspect of what is claimed. Applicant argues that the Soos reference does not teach contact with cells producing an allergen-specific IgE. Applicant states that a person of ordinary skill would not have known what amount of interferon tau would be effective for suppressing or inhibiting allergen-specific IgE effects. Applicant also notes that administering interferon tau to a patient as disclosed in the cited references would not necessarily result in such contact. Applicant's arguments have been fully considered but are not persuasive.

The issue in in re Crown Operations was whether the limitation was necessarily present and it was held that the presence of this limitation was not established by Crown Operations. In the instant application, there is no difference in method steps between what is taught in the prior art and what is claimed by Applicant. There is nothing different about Applicant's administration of interferon tau. Since Applicant's invention is presumed to be enabled, it is obvious to the artisan of ordinary skill that the result taught by Applicant must necessarily have occurred when the identical method was performed, whether it was recognized at the time or not.

MPEP 2112 provides the following: The fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic. In re Rijckaert, 9 F.3d 1531, 1534, 28 USPQ2d 1955, 1957 (Fed. Cir. 1993) (reversed rejection becausenherency was based on what would result due to optimization of conditions, not what was necessarily present in the prior art); In re Oelrich, 666 F.2d 578, 581-82, 21 USPQ 323, 326 (CCPA 1981). "To establish inherency, the extrinsic evidence must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.' " In re Robertson, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999) (citations omitted) (The claims were drawn to a disposable diaper having three fastening elements. The reference disclosed two fastening elements that could perform the same function as the three fastening elements in the claims. The court construed the claims to require three separate elements and held that the reference did not disclose a separate third fastening element, either expressly or inherently.).

and

"In relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art." Ex parte Levy, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990) (emphasis in original (Applicant's invention was directed to a biaxially oriented, flexible dilation catheter balloon (a tube which expands upon inflation) used, for example, in clearing the blood vessels of heart patients). The examiner applied a U.S. patent to Schjeldahl which disclosed injection molding a tubular preform and then injecting air into the preform to expand it against a mold (blow molding). The reference did not directly state that the end product balloon was biaxially oriented. It did disclose that the balloon was "formed from a thin flexible inelastic, high tensile strength, biaxially oriented synthetic plastic material." Id. at 1462 (emphasis in original). The examiner argued that Schjeldahl's balloon was inherently biaxially oriented. The Board reversed on the basis that the examiner did not provide objective evidence or cogent technical reasoning to support the conclusion of inherency.).

In the instant situation, the methods are the same. There are no missing steps or differences in administration. Thus, by analogy, thre are no missing fastening elements and no changes in orientation. Thus if the methods of the prior art were practiced in a patient suffering from IgE-mediated allergy, that condition was inherently treated in the prior art. Since IgE mediates acute allergic response, it mediates the allergic responses that are common in the general population, including those who suffer from autoimmune disease and other immune-related disorders. Treatment of patients with these problems would inherently treat IgE-mediated allergy in these same patients. The patients suffering from IgE-mediated allergy would also be in need of treatment of this allergy, so Applicant's amendment does not distinguish over the prior art. The method of treatment is the same as claimed by Applicant and the population treated includes those with the condition that Applicant intends to treat. Furthemore, contact with the appropriate cells would inherently occur upon administration of the interferon. Neither this contact nor its effect need have been known in order for said contact and said effect to have occurred. Applicant's method has been used to treat a patient population that includes many suffereing from the condition Applicant intends to treat and who are in need of such treatment. Thus contact, effect, and treatment have occurred, regardless of whether they were known to have occurred. Furthermore, Applicant claims no differences in the amount to be administered that would serve to distinguish the method from that taught in the prior art.

WIth respect to claims 54 and 55, they were rejected as anticipated by the '286 patent because of the requirement for chimeras. There is no requiremtnt in the claims that administration be in vitro and that was not the basis for the rejection.

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